

KO11685
JUL 31 2001

Exhibit D

510(k) Summary

Submitted by: Daniel J. Manelli
Manelli Denison & Selter, P.L.L.C.
2000 M Street, NW (Suite 700)
Washington, DC 20036

Telephone: 202-261-1000

On behalf of Tokuyama America, Inc.
510(k) Submission: Bistite II DC
May 30, 2001

The product is a dental cement which can be either light cured or self cured. It is intended for use in the cementation of dental devices, luting, repair of fractured procelains or crown and bridge resins, cementing of adhesive bridges and CR core posts.

The product is for use only by dental practitioners; it is not intended for OTC use. It contains materials that pose no health hazard when used according to directions and has received the approval of the Japanese Government. It is substantially equivalent to various marketed dental cement products, including the following:

Bistite II SC (Tokuyama)	K991711
Panavia 21 (Kurarey)	K933030
C&B Metabond (Parkhill)	K960464

The use of the product is contra-indicated for patients who are hypersensitive to methacrylate monomers. It should not be allowed to come into contact with skin, eyes or clothing. Should contact with the eyes occur, the eyes should be thoroughly flushed with water followed by immediate contact with a physician.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2001

Tokuyama America, Incorporated
C/O Mr. Daniel J. Manelli
Attorney
Manelli, Denison & Selter, P.L.L.C
2000 M Street, NW Suite 700
Washington, D.C. 20036

Re: K011685
Trade/Device Name: Bistite II DC
Regulation Number: 872.3275
Regulatory Class: II
Product Code: EMA
Dated: May 30, 2001
Received: May 31, 2001

Dear Mr. Manelli:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

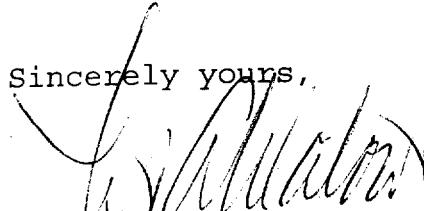
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Timothy A. Ulatowski

Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit C

Page 1 of 1

510(k) Number (if known): K011685

Device Name: Tokuyama Bistite II DC

Indications For Use:

For use as a dental cement in various applications, including luting, repair of fractured procelains or crown and bridge resins, cementation of adhesive bridge prostheses and CR core posts.

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device evaluation (ODE)

Susan Runn
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011685

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____